Attorney Docket No. 9233-46 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.
Application Serial No.: 10/075,097
Filed: February 13, 2002
For: *METHODS OF TREATING DIABETES MELLITUS*

Declaration of James Gordon Still Under 37 C.F.R. § 1.132

Sir:

I, James Gordon Still, hereby declare as follows:

1. I am a named co-inventor on U.S. Patent Application Serial No. 10/075,097, entitled "Methods of Treating Diabetes Mellitus," filed February 13, 2002 and claiming priority under 35 U.S.C. § 119(e) to provisional application serial number 60/269,2001, filed February 15, 2001. The other co-inventors on this application are Christopher H. Price, Nnochiri N. Ekwuribe and Jennifer Ann Filbey. Additional co-inventors Aslam M. Ansari, Amy L Odenbaugh and Balasingam Radhakrishnan have been added to this application as set forth in a Request to Correct Inventorship Under 37 C.F.R. § 1.48(c), filed September 30, 2003.

2. I was an invited speaker at the VI International St. Barts Symposium entitled "Diabetes 2000: Therapy and Technology" and gave an oral presentation to an audience of about 60-70 attendees at that meeting in London, England on May 12, 2000. I prepared a set of slides using Power Point® software to present during my talk, a copy set of which is submitted herewith in the attached supplemental Information Disclosure Statement. These slides were displayed during my presentation, which lasted about 45 minutes. I controlled the display of each slide by personal operation of a laptop computer. No copies of the slides were available to the public at any time either before or after my presentation.

3. I gave an oral presentation to an audience of about 60-80 attendees at the 2001 Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics in Orlando, Florida on March 9, 2001. I prepared a set of slides using Power Point® software to present during my talk, a copy set of which is submitted herewith in the attached supplemental Information Disclosure Statement. These slides were displayed during my presentation, which lasted about 20 minutes. I controlled the display of each slide by personal operation of a laptop computer. A handout was available at the presentation but no copies of the slides were available to the public at any time either before or after my presentation.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

James Gordon Still

Nov. 24 2003
Date

*530 F. Supp. 846, *; 1981 U.S. Dist. LEXIS 14892, **;*
210 U.S.P.Q. (BNA) 727

REGENTS OF the UNIVERSITY OF CALIFORNIA and Wright Manufacturing Company, Plaintiffs, v. HOWMEDICA, INC., Defendant

Civ. No. 76-449

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

530 F. Supp. 846; 1981 U.S. Dist. LEXIS 14892; 210 U.S.P.Q. (BNA) 727

March 12, 1981

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiffs sued defendant for patent infringement for the manufacture and sale of a knee prosthesis that allegedly violated their patent; defendant asserted that plaintiffs executed fraud on the Patent and Trademark Office in the procurement of their patent.

OVERVIEW: Plaintiffs sued defendant for patent infringement after defendant manufactured and sold a knee prosthesis that plaintiffs believed violated a patent they held. The court first held that the plaintiffs' invention was patentable, finding it novel where implantation outside the one year grace period was experimental and certain printed publications and lecture materials did not bring the knee into the public domain, and finding it nonobvious where prior art differed significantly from the claims of plaintiffs' patent. Next, the court rejected defendant's allegations of fraud in the procurement of plaintiffs' patent where changes made in the application were not substantial and were not intended to deceive or mislead. Finally, the court found that defendant's knee did not infringe plaintiffs' patent because the doctrine of file wrapper estoppel precluded plaintiffs from recapturing the initial breadth of their patent application after they voluntarily narrowed it in the application process.

OUTCOME: The court entered judgment for defendant where, although plaintiffs' knee prosthesis was patentable because it was novel, useful, and nonobvious, and although plaintiffs did not commit fraud in procuring their patent, plaintiffs had narrowed the scope of their patent through the doctrine of file wrapper estoppel.

CORE TERMS: patent, knee, invention, inventor, femoral, surface, curve, prosthesis, groove, tibial, implantation, experimental, radii, infringement, condyle, declaration, upper surface, patentability, subject matter, constantly, lecture, slide, skill, continuously, orthopaedic, downwardly, revisions, rotation, catalog, invalid

LexisNexis (TM) HEADNOTES - Core Concepts - ✦ Hide Concepts

Patent Law > Novelty & Anticipation
Patent Law > Utility Requirement
Patent Law > Nonobviousness

HN1 The statutory conditions of patentability, as set forth in 35 U.S.C.S. §§ 101-103, are novelty, utility and nonobviousness. More Like This Headnote

Patent Law > Novelty & Anticipation

HN2 Novelty or newness of an invention or discovery is the keystone to patentability. More Like This Headnote

Patent Law > Novelty & Anticipation

HN3 The Patent Act, 35 U.S.C.S. § 102, sets forth the types of activity which negate novelty and render an invention or discovery unpatentable. See 35 U.S.C.S. § 102. More Like This Headnote

Patent Law > Novelty & Anticipation
Patent Law > Statutory Bars > Public Use
Patent Law > Statutory Bars > On Sale

HN4 The critical date indicates the commencement of the one year grace period during which an inventor has the opportunity to engage in commercial activity without prejudice to his right to secure a patent. The existence and length of this period reflects a balance of (1) the inventor's interest in determining whether or not a patent is desired following sales and in having a sufficient amount of time to prepare and file a patent application, with (2) the public interest in preventing an inventor from concealing his invention from the public, while using it to his commercial advantage more than one year prior to his patent application, and thus extending the period of his monopoly beyond that protected by the patent laws. More Like This Headnote

Patent Law > Statutory Bars > Experimental Use
Patent Law > Nonobviousness > Date of Invention

HN5 The purpose of the experimentation exception to the 35 U.S.C.S. § 102(b) bar is to allow the inventor sufficient time to perfect his invention. An invention is perfected for purposes of patentability once it has been reduced to practice by sufficient testing and experimentation to demonstrate its utility. Thus, the use by an inventor, in good faith, for the purpose of testing his apparatus before it has been reduced to practice, is not a public use within the scope of the statute, even if accidental to such use he derives some financial return. Similarly, a sale which meets the same qualifications will not render a product unpatentable. More Like This Headnote

Patent Law > Statutory Bars > Experimental Use

HN6 In proving the experimental nature of an invention, the patent owner has the burden, which must be satisfied by clear and convincing evidence. More Like This Headnote

Patent Law > Statutory Bars > Experimental Use
Patent Law > Statutory Bars > On Sale

HN7 A single instance of sale or offer to sell prior to the critical date will render a patent invalid. Notwithstanding facts sufficient to raise the statutory on sale bar, a patent may be valid if the sale or offer to sell was primarily for the purpose of experimentation. More Like This Headnote

Patent Law > Statutory Bars > Public Use

HN8 A printed publication prior to the critical date which describes the invention will preclude entitlement to a patent. More Like This Headnote

Patent Law > Statutory Bars > Public Use

HN9 To constitute a publication, within the meaning of the statute, the invention must be described sufficiently to impart to a person with ordinary skill and knowledge of the prior art the information needed to devise the invention without further genuine inspiration or undue experimentation. More Like This Headnote

Patent Law > Statutory Bars > Public Use
Patent Law > Statutory Bars > Experimental Use
HN10 The publication bar is based upon the theory that an idea once published is in the public domain, and that no consideration can be offered thereafter in exchange for the grant of a patent monopoly. For this reason, and for the protection of the reasonable expectations of the public, the experimental use doctrine does not apply to overcome the printed publication bar. More Like This Headnote

Patent Law > Nonobviousness > Tests & Proof of Obviousness
HN11 See the Patent Act, 35 U.S.C.S. § 103. Patentability thus depends upon the non-obvious nature of the subject matter sought to be patented to a person having ordinary skill in the prior art. Under the Patent Act, 35 U.S.C.S. § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. In addition, secondary considerations such as commercial success, long felt but unsolved needs, failure of others, etcetera, may be relevant as indicia of obviousness.

Patent Law > Originality > Joint & Sole Inventions
HN12 A presumption of validity generally attaches to a patent, and the burden of proving invalidity rests upon the defendant. More Like This Headnote

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
Patent Law > Infringement > Defenses
HN13 Fraud in the procurement of a patent is a valid defense in a suit for patent-infringement. This defense is based upon the social and economic consequences of a patent which give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct. More Like This Headnote

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
Patent Law > Infringement > Defenses
HN14 An applicant for a patent, therefore, is held to the highest standards of honesty and candor in presenting his bid for a patent to the Patent and Trademark Office (Patent Office). In this regard, there is no rational basis for a distinction between affirmative misrepresentations and misleading omissions. If such misrepresentations or omissions are present, they must be material in order to affect the validity of the patent. The test of materiality, however, is a liberal one. In addition to misrepresentations which are material, a finding of fraud must be based upon a finding of, at the least, gross negligence or recklessness in representing the facts to the Patent Office. More Like This Headnote

Patent Law > Inequitable Conduct > Materiality, Scienter & Effect
Patent Law > Infringement > Defenses
HN15 See 37 C.F.R. § 1.56.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Filing Requirements
HN16 See 37 C.F.R. § 1.56.

Patent Law > Infringement > Burdens of Proof
HN17 The burden of proving infringement by a preponderance of the evidence rests upon the plaintiff. More Like This Headnote

Patent Law > Infringement > Acts of Infringement
HN18 The standard of infringement is not whether the embodiment of the patent is infringed, but whether the claims of the patent are infringed. More Like This Headnote

Patent Law > Infringement > Claim Interpretation
Patent Law > Infringement > Acts of Infringement
HN19 To establish infringement, each element in the patent claim must be incorporated in the accused device. More Like This Headnote

Patent Law > Infringement > Doctrine of Equivalents
HN20 The doctrine of equivalents protects a patent holder from devices that differ merely in name, form or shape from the patented invention. Thus, minor deviations from the literal scope of the patent claims will not elude the reach of the patent's protection. More Like This Headnote

Patent Law > Infringement > Doctrine of Equivalents
Patent Law > Infringement > Prosecution History Estoppel
HN21 In some situations, it is unnecessary to reach the issue of equivalence. In these situations, the history of the prosecution of the patent, contained in a file wrapper, reveals that the patentee has surrendered claims, or has amended, narrowed, or otherwise limited his claims in response to objections of the Patent and Trademark Office. More Like This Headnote

Patent Law > Infringement > Doctrine of Equivalents
Patent Law > Infringement > Prosecution History Estoppel
HN22 If an applicant consents to the demands of the Patent and Trademark Office in order to obtain the patent, such consent operates as a disclaimer, and the applicant is thereafter bound by it. More Like This Headnote

Patent Law > Infringement > Doctrine of Equivalents
Patent Law > Infringement > Prosecution History Estoppel
HN23 The doctrine of file wrapper estoppel precludes a patent holder from later recapturing the breadth which was given up in the Patent and Trademark Office to secure approval of the application. More Like This Headnote

COUNSEL: [1]**

Carella, Bain, Gilfillan & Rhodes by R. Gale Rhodes, Jr., and Jeffrey L. Miller, Newark, N. J., for plaintiffs.

Howard W. Hermann, Dow-Corning Corp., Midland, Mich., of counsel for plaintiff Wright Manufacturing Co.

Shanley & Fisher by Frank L. Bate, Newark, N. J., Stanton T. Lawrence, III, Pennie & Edmonds by John Kidd, and F. V. Calvetti, New York City, for defendant.

OPINIONBY: SAROKIN

OPINION: [*848]

OPINION

Plaintiff The Regents of the University of California is the owner of U. S. Patent No. 3,869,731 and plaintiff Wright Manufacturing Company is the exclusive licensee of that patent. Plaintiffs have brought this action pursuant to 35 U.S.C. § 1 et seq. alleging infringement of the patent by defendant Howmedica, Inc. This court has jurisdiction pursuant to 28 U.S.C. § 1338(a).

FINDINGS OF FACT

PARTIES AND STANDING

1. Plaintiff The Regents of the University of California (hereinafter "Regents") is **[*849]** a California corporation. Regents has been the owner of record of United States Letters Patent No. 3,869,731 for an Articulated Two-Part Prosthesis Replacing the Knee Joint, Theodore R. Waugh, Richard C. Smith, Sanford H. Anzel and Caesar F. Orofino, inventors **[**2]** (hereinafter the "Waugh Patent") since its issuance on March 11, 1975. (Exh. P-1)

2. Plaintiff Wright Manufacturing Company (hereinafter "Wright") is a Tennessee corporation. By written Agreement dated August 3, 1973, Regents granted to Wright the exclusive rights throughout the United States of America to make, use and sell the invention described and claimed in the Waugh Patent; and since that date Wright has been and still is so licensed.

3. Wright, at all times relevant hereto, has been engaged in the business, inter alia, of manufacture and sale of orthopaedic devices including knee prostheses; in particular Wright has been engaged in the manufacture of a knee prosthesis catalog Nos. 1301 and 1302, which embody the invention of the Waugh Patent.

4. UCI is an acronym for University of California at Irvine. UCI is a trademark employed by Wright in association with the manufacture, advertising and sale of the knee prosthesis embodying the invention of the Waugh Patent (hereinafter "UCI Knee"), from its first introduction in the market.

5. Defendant Howmedica, Inc. (hereinafter "Howmedica") is a Delaware corporation maintaining a principal place of business in New Jersey. It **[**3]** has manufactured a variety of knee prostheses from the early 1930's through the present.

DEVELOPMENT OF THE INVENTION

6. The invention of the Waugh Patent was developed over a period of time by four orthopaedic surgeons associated with the University of California at Irvine (UCI). The inventors are Theodore Waugh, Richard Smith, Caesar Orofino, and Sanford Anzel. (Exh. P-1)

7. One of the surgeons, Dr. Waugh, initially tried to interest Howmedica in assisting in the development of the invention. Howmedica took no interest in the matter at that time for reasons which are not relevant herein.

8. Thereafter, the surgeons engaged Wright to do the developmental assistance. Wright invested time and expense in the making of drawings and models and in underwriting prosecution of the patent application. Wright undertook this task with the expectation of being awarded an exclusive patent license, which it in fact secured. (Exh. P-2)

9. Wright worked with the surgeons and produced prototype knees that were tested in

cadavers and machines. By the end of 1971 the doctors were ready to test the knee in a living patient.

10. The first implantation of the UCI Knee in a living human was **[**4]** made on January 12, 1972. (The critical date is February 14, 1972, which is the last date not more than one year before the filing date of the application for the Waugh Patent.) The implantation was made on a Mr. George Jessen. The operation was performed by Dr. Waugh with the assistance of Dr. Orofino. Dr. Anzel and Dr. Smith were in attendance. Approximately nine people assisted the operation while others observed the procedure.

11. The implantation attracted the attention of the news media, and certain accounts of it were published. (Exh. DX-23, 24, 25, 27)

12. Dr. Waugh regarded the implantation in Jessen to be of an experimental character. He considered the operation on Jessen not to have been a success. The next implantation in a living human was in March of 1972.

13. A lecture by Drs. Waugh and Smith was given to physicians at the 101st Annual Session of the California Medical Association on February 12, 1972, just two days prior to the critical date.

14. The California Medical Association is an association of medical doctors in the **[*850]** State of California. About 30 people attended the presentation. The Index to Participants (Exh. DX-32) shows international **[**5]** participation at the meeting and guests were also brought by the participants. There was no confidence or secrecy required of the participants. A press conference was held after the meeting.

15. Wright had no knowledge of the lecture, had no salesmen there, and had no brochures on the knee in existence at that time.

16. Dr. Smith gave a lecture which dealt with the development of the UCI Knee. In connection with this lecture, he displayed projections of certain slides which showed pictures and drawings of the UCI Knee. The transient projection of such slides at the aforementioned lecture could not and did not adequately disclose the invention claimed in the Waugh Patent to the extent necessary to teach a person of ordinary skill in the art to make or use the invention, even if the slide presentation as depicted in Exh. DX-36 described the essential elements of the patent claims. (Exh. DX-33, DX-36 and DX-38)

17. The public did not have access to the slides themselves prior to the critical date. No prints of the slides were made prior to said critical date.

18. Dr. Smith's statements concerning the experimental character of the Jessen Implantation are set forth in the text **[**6]** of his speech before the California Medical Association wherein he stated:

> "The patient had a good clinical ligamentous stability pre-operative, was in generally good health otherwise, was working and apparently well motivated, and only 52 years of age. He was presented at the hospital's weekly orthopaedic conference, and after thorough explanation as to the experimental nature of the procedure and also the fact that he may still come to fusion if it failed, he was asked if he would be interested in becoming our first candidate."

(Exh. DX-33, p. 5)

19. During the same speech, which was only two days prior to the critical date, Dr. Smith also stated:

> "At the present time, the patient is out of his cylindrical cast, ambulating cautiously with crutches, without pain in his knee, being encouraged to overcome his initial apprehension in ranging his new knee, and giving us hope that the design will warrant further trial."

(Exh. DX-33, p. 6)

20. Dr. Smith also stated in his speech:

> "This discussion is an attempt to give the audience some insight into what goes on in evolution of any medical contrivance, and hopefully not interpreted as a sales campaign for any **[**7]** design in particular. We are understandably excited about the future of our own design during these early stages of its development, and beg your indulgence at this time."

(Exh. DX-33, p. 6)

21. Dr. Waugh's presentation dealt mainly with operating techniques, and there is no evidence to establish that Dr. Waugh distributed any printed publications describing the invention of the Waugh Patent.

22. Wright assigned a catalog number to the UCI Knee prosthesis prior to shipment of the knee prosthesis that was implanted in Mr. Jessen. (Exh. DX-28)

23. Wright ascribed a catalog number to the knee prosthesis at that time to maintain specific records of that which it would eventually ship and to have a catalog number ready so that some indeterminate future time the knee prosthesis could be offered for sale and sold.

24. Wright and Dr. Waugh agreed that Wright would furnish nonclinical experimental knee prostheses free of charge, but that Wright would be paid for clinical experimental knee prostheses.

25. The amount charged by Wright was less than Wright's cost in making the unit shipped. Although the charge was never collected, Wright made several repeated attempts to bill the **[**8]** University and Veterans Administration Hospital.

26. The bill was later rescinded and never rebilled. Although such actions may **[*851]** have been motivated by a concern for the ultimate validity of the patent, the sale, nonetheless, was for experimental and not commercial use.

27. The inventors of the Waugh Patent or the Regents made no attempt to offer the UCI

Knee for sale prior to the critical date. The first sale of any UCI Knee for implantations by doctors other than the inventors was in August of 1972, and formal offering for sale to the orthopaedic community at large occurred in the fall of 1972. The court so concludes notwithstanding that the femoral and tibial components claimed in the "731 patent were assigned commercial catalog numbers 1301 and 1302 respectively in December 1971; that a "sale" occurred on December 31, 1971 as reflected in invoice Exh. DX-28; that the December 1971 and August 1972 invoices were identical sales forms; that the December 1971 invoice Exh. DX-28 tracks the August sales invoice in every detail; that in the December 31, 1971 Invoice (Exh. DX-28), Wright sold two Catalog No. 1301 femoral components for $ 325.00 each and two Catalog No. **[**9]** 1302 tibial components for $ 175.00 each to the University; that the sale terms were net thirty (30) days, f. o. b. Memphis, Tennessee (Exh. DX-28); that during 1972, Wright made efforts to collect on the invoice; and that on January 7, 1972, in Invoice No. 106,243, Wright sold the University one knee femoral template guide for $ 325.00 on the same sale terms. (Exh. DX-29)

28. Wright made no attempt to sell a UCI Knee for any purpose other than implantation by the inventors for experimental purposes prior to the critical date.

29. Any and all uses of the UCI Knee prior to the critical date were experimental and noncommercial in nature and were performed by the inventors.

30. Howmedica was and continues to be interested in knee prostheses. Howmedica was interested in an improved device that it had first manufactured for Dr. Waugh in 1970. In December of that year, Howmedica sent Waugh a prototype femoral component and a MacIntosh tibia component. Letters, meeting and discussions took place concerning the 6439 knee. These involved structural changes to improve fixation and to prevent warping and to include new dimensions for the knee. In 1973, Howmedica continued engineering **[**10]** development of the knee with Dr. Waugh's supervision at the Howmedica plant.

31. Employees of Howmedica examined a UCI Knee manufactured by Wright and obtained its dimensions. Howmedica obtained one such knee manufactured by Wright and thoroughly analyzed it, including its dimensions, prior to finalizing the design of its competitive knee, catalog 6439. After these evaluations by Howmedica and several members of the orthopaedic community that act as advisers to Howmedica, a revised design was then developed by Howmedica during 1973 to compete with the Wright design. Howmedica spent over 75 man hours developing the engineering aspects of the 6439 knee prosthesis and over 200 man hours developing the necessary tooling to make the prosthesis that is identified in a contemporaneous engineering report. (Exh. DX-75)

32. Howmedica decided to produce a version of the UCI Knee because it perceived the UCI Knee to have market acceptability in that the UCI Knee was designed to provide for flexion and extension while retaining the cruciate ligament. Howmedica produced its knee with the guidance and approval of the inventors of the UCI Knee. Dr. Waugh showed Howmedica the UCI Knee in his **[**11]** office and expressed dissatisfaction with it. Changes were discussed including changes in size. Howmedica sought to improve upon the UCI Knee with Dr. Waugh's cooperation and hoped that the 6439 knee would provide several improvements over the Wright version of the 6439 knee. Dr. Waugh hoped to produce a knee that was an improvement over his own UCI Knee. Dr. Waugh published an article in 1976 in which he stated that the UCI Knee had a failure rate requiring reoperation ranging from 10 to 20 per cent.

[*852] 33. Dr. Waugh became disenchanted with Wright and felt that if there were to be any further work on the knee device, he was content to do it with Howmedica rather than Wright. While developing its own prosthetic device, Howmedica sought to negotiate a licensing agreement with Wright. Prior to the meeting with Dr. Waugh, Howmedica was not aware of a patent application nor a licensing agreement with Wright. During the meeting

Howmedica became aware of these matters. Confronted with this information, Howmedica decided to pursue both a licensing agreement and development of the product. Howmedica did not make any misrepresentations to Dr. Waugh or influence him to develop **[**12]** a product he did not desire to develop.

34. Howmedica did, in fact, seek a license from Wright but no agreement was reached. In October of 1973 Messrs. Keller and Bennett of Howmedica visited Mr. Rylee in Memphis to discuss the matter. Mr. Rylee explained that such a license could only be acceptable if it protected Wright's developmental investment and expected patent monopoly in a manner sufficient to protect Wright's salesmen who worked on commission and who could not compete one on one with Howmedica's more developed sales organization. In essence, Mr. Rylee was unwilling to sublicense if it meant putting his sales force out of business.

35. Howmedica, through Mr. Keller, then advised Mr. Rylee that Howmedica would go to market with a copy of the UCI Knee; that if a patent issued on the UCI Knee, Wright would be forced to sue; and if Wright did sue, Howmedica would keep the case in court for a number of years sufficient to allow Howmedica to protect its market position by continuing to sell its copy of the UCI Knee until a subsequent generation of knee prostheses came along. Mr. Keller advised Mr. Rylee that he believed that Wright was of insufficient financial resources to **[**13]** sustain such a legal battle.

36. Howmedica thereafter manufactured and offered for sale a knee prosthesis first called the Howmedica Vittalium Irvine Total Knee Prosthesis substantially similar to the Wright UCI Knee, and Howmedica first displayed its Howmedica Vitallium Irvine Total Knee Prosthesis in January 1974 at an annual convention of the American Academy of Orthopaedic Surgeons in Dallas, Texas. Howmedica used the word "Irvine" in its promotional literature distributed in association with the promotion of the Howmedica 6439 Total Knee Prosthesis. Wright had previously been marketing its UCI Knee under the trademark "UCI", which stands for the University of California at Irvine.

37. Wright instituted suit in the United States District Court for the Northern District of Texas and obtained a temporary restraining order against further dissemination by Howmedica of the promotional literature using the word "Irvine".

38. Howmedica also copied four instruments for implantation of the knee that had been designed and patented by Mr. Rylee of Wright. In fact, in promoting its instruments, Howmedica displayed photographs of instruments actually manufactured by Wright.

39. Howmedica **[**14]** also copied holes in the central fixation fin of the femoral component of the knee. Wright subsequently removed these holes in the UCI Knee since they were found to be unnecessary, and thereafter Howmedica removed the holes from the 6439.

40. Mr. Rylee spoke to Mr. Keller at the aforesaid Dallas, Texas convention and reminded him of the pendency of the patent application on the Waugh Patent. Mr. Keller again stated Howmedica's intention to market its knee prosthesis with or without a license.

41. When Wright sued Howmedica at the time of the Dallas convention, Wright affirmatively pleaded the existence of the application for the Waugh Patent. (Exh. P-3)

42. Howmedica, after being enjoined against use of the word "Irvine" in connection with the promotion and sale of its total knee prosthesis, restricted the name of its **[*853]** total knee prosthesis to Howmedica 6439 Total Knee. Howmedica took a license on the instruments only, and the parties specifically reserved rights to enforce subsequently issued patents. (Exh. P-3)

43. The patent in suit, the Waugh Patent, issued on March 11, 1975 (Exh. P-1). On May 13,

1975, Howmedica became aware of the issuance of the Waugh Patent. **[**15]** (Exh. DX-84)

44. After becoming aware of the issuance of the Waugh Patent and Wright's demand to cease infringement in May 1975, Howmedica continued the manufacture and sale of the Howmedica 6439 Total Knee until January 1980. The 6439 Knee was deleted from the Howmedica catalog of January 1980. 1979 sales were insignificant (less than 100 units).

45. As the result of an examination and comparison of the engineering drawings and as-built drawings for the respective knee prostheses, an examination and comparison of the respective knee prostheses, and the testimony of engineers presented as witnesses in this matter, the court finds that the accused Howmedica 6439 Total Knee was designed by deliberately and substantially copying the Wright UCI Knee with the following differences: (The significance of such differences will be discussed hereinafter.)

a. Exhibit DX-73 shows that only two radii are used and that a continuously changing curve of constantly decreasing radii does not exist in the 6439, that is, the 6439 device does not have an infinite number of curves.

b. Exhibit DX-74 illustrates that there is no C-shaped groove in the upper articulating surface that follows the C-shaped **[**16]** plan of the component.

c. Exhibit DX-74 also shows two concave tracks in the upper plateau surface neither of which are C-shaped nor have a uniform cross-sectional shape and shallow depth throughout their length.

d. Neither does the 6439 Knee have in each transverse cross-section a curve forming part of a circle of constant cross-section.

FACTS RELATING TO DEFENDANT'S "FRAUD ON THE PATENT OFFICE" DEFENSE

46. The development of the disclosure of the invention of the Waugh Patent was managed by Mr. Rylee.

47. Mr. Rylee's development of the disclosure entailed numerous meetings, telephone conversations, and correspondence with the inventors, as well as Mr. Scrivener, Wright's patent attorney.

48. Prior to the time that the inventors executed the Declaration, Power of Attorney and Petition that was filed with the patent application, several drafts of the patent application had been made, some by Mr. Rylee and at least one by Mr. Scrivener. (Exh. DX-43) There is no evidence that the completed application was shown to all of the inventors. Dr. Waugh never communicated with Mr. Scrivener nor was Dr. Waugh consulted about prosecution of the "731 patent application. Dr. Waugh never **[**17]** consulted Drs. Anzel or Orofino about changes to the application and did not recall whether he ever received a copy of the final version of the application. Preparation and prosecution of the application for the "731 patent was controlled by Mr. Rylee. The original draft of the patent application was prepared by Mr. Rylee. There is no evidence that the completed application as filed by Wright was ever shown to or reviewed by the inventors prior to filing. The inventors did not read the application and claims as filed on February 14, 1973, when executing the declaration form on November 14, 1972.

49. There is no evidence that the inventors revised the patent application or that they were aware of and approved the revisions prior to its filing.

50. The inventors signed the Declaration on November 14, 1972. No application was attached

to the declaration form when it was executed. Although a draft may have been in existence and present when the declaration was executed, it was not the application which was filed with the Patent Office.

[*854]

51. There were changes made to the patent application subsequent to November 14, 1972. The Declaration, however, was not re-executed, **[**18]** and was filed with the final application on February 14, 1973.

52. There is no evidence that the completed application as filed by Wright was ever shown to or reviewed by the inventors prior to filing with the Patent Office.

53. Mr. Richard Wahl, Howmedica's expert witness on Patent Office Procedure, testified that there were three areas of post-oath revisions that gave him concern and for which he believed the Patent Office would have stricken the application had it known of the revisions:

a. The first area concerns changes in the range of motion attributable to the human knee, as set forth in the Background of the Invention.

b. The second area concerns the apparent reversal of figures of the drawings.

c. The third area entails the bifurcation of the claims, resulting in an additional claim being added.

54. The changes made subsequent to November 14, 1972 were not substantial changes. They were not considered by the inventors as substantial, and the application as filed set forth their claimed invention.

55. The changes made subsequent to November 14, 1972 were not made with any intent to deceive or mislead the Patent Office or the public, and did not materially affect the **[**19]** prosecution of the application.

56. The Patent Office would not necessarily have stricken the application if it had been made aware of the post-oath revisions, although it may have done so and had the right to do so. Commissioner Wahl, Commissioner of the Patent Office, had ordered applications to be struck from the Patent Office files for similar revisions.

57. Counsel's conduct in filing an application with minor post-oath revisions was not in accordance with the prevailing Patent Office rules.

58. In the course of the prosecution of the patent, three affidavits were filed in the Patent Office on behalf of the Regents, one of Dr. Tooms, one of Dr. MacFarland, and one of Mr. Rylee. (Exh. DX-5)

59. There is nothing in the record to support a finding that said affiants knowingly made any incorrect statements or exaggerations notwithstanding claimed inaccuracies regarding the rotational characteristics of the Polycentric knee, the Geomedic knee, and the shape of the femoral condyles.

60. None of the prior art references upon which Howmedica relies are more pertinent to the subject matter of the Waugh Patent than those cited by the examiner in the course of the prosecution of the **[**20]** patent, including the Gunston article, the Der Chirung article, and Drs. Frankel's and Burstein's work on instant centers.

61. Mr. Rylee filed an affidavit in the Patent Office disclosing pictures of the Geomedic knee

(which is the Averill patent) and the Polycentric knee (which is the Gunston reference), and brought samples of those knees to show the examiner at an interview. (Exh. DX-5)

62. The only prior art relied upon by Howmedica that Mr. Rylee knew of but did not call to the attention of the Patent Examiner was prior art either cited by the Examiner (Link patent, which is the St. Georg Sled; MGH prosthesis) or otherwise known to the examiner through participation in issuance of the prior art patent involved (Johnston patent). (Exhs. P-1 and DX-8) Mr. Rylee conducted a prior art search and was intimately acquainted with the prior art. He reviewed all the available literature relating to knees. Mr. Rylee admitted being aware of the Johnston patent, the St. Georg Sled, the MGH femoral component and the Geometric knee n1 during the time the patent application was pending before the Patent Office.

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n1. The geomedic and geometric devices are substantially the same marketed under two different names.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - - **[**21]**

[*855] The St. Georg Sled (Exh. DX-13) is a modification of Link and was known by Wright but not cited to the Patent Office.

The Johnston patent (Exh. DX-17) should have been disclosed to the Patent Office. Wright's own expert so concedes. However, the examiner who issued this reference also issued the "731 patent, suggesting that he was already aware of Johnston.

63. The invention described in the Waugh Patent is a two-part knee prosthesis. One part, the femoral component, consists of a unitary body having two substantially parallel runners generally following the contour of the normal femoral condyles, the runners being held together by a system of bone fixation of the runners into the distal end of the femur. The femoral component coacts with a circular disc shaped tibial component which is fixed to the tibia and which is generally C-shaped and has in its upper surface a C-shaped circular groove which mates with the runners of the femoral component to allow relative motion between the components in both hinge-type flexion and extension and rotation at the same time. However, the issue of infringement only concerns a description of the claimed invention. Claim 1 of **[**22]** the patent specifically defines the patented combination of elements, while claims 2 and 3 are directed to the femoral and tibial components respectively. (Exh. P-1)

64. The C-shaped groove, particularly a circular C-shaped groove, in the upper surface of the tibial component of the claimed invention, in combination with the downwardly facing bearing surfaces of the femoral component of the claimed invention which downwardly facing bearing surfaces in the anterior to posterior shape which are a continuously changing curve of constantly increasing radii and which in the transverse cross-sectional shape are a curve forming part of a circle and of shallow depth, provides substantial line contact during articulation occasioned by flexion of the knee and during rotation occasioned by rotation of the femur with respect to the tibia, and thereby provides line contact resulting in improved wear characteristics.

65. The differences between the combination of elements set forth in claim 1 of the Waugh Patent and the prior art are not such that said combination as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the orthopaedic or biomechanic **[**23]** arts.

66. The differences between the combination of elements set forth in claim 2 of the Waugh Patent and the prior art are not such that said combination as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the orthopaedic or biomechanic arts.

67. No tibial component is to be found in the cited prior art which component is provided in its upper surface with a circular C-shaped groove for receiving the downwardly extending bearing surface of the femoral component to permit flexion and axial rotation of the knee.

68. No tibial component is to be found in the prior art which is provided on its upper surface with a C-shaped groove, particularly a circular C-shaped groove, for receiving the support members of a femoral component, and wherein the groove is of uniform cross-sectional shape and shallow depth throughout its length and its bottom shaped in each transverse cross-section as a curve forming part of a circle.

69. The differences between the combination of elements set forth in claim 3 of the Waugh Patent and the prior art are not such that said combination as a whole would have been obvious at the time the invention was **[**24]** made to a person having ordinary skill in the orthopaedic or biomechanic arts.

70. The structural elements of the tibial and femoral components of the prosthetics disclosed in the prior art cited by the defendant in alleging invalidity of the claims of the patent in suit are the same, or substantially the same, as the structural elements in the prior art cited by the United States Examiner in the prosecution of the patent in suit.

[*856] FACTS PERTAINING TO INFRINGEMENT

71. Defendant's 6439 Total Knee Tibial Component is disc-shaped and its purpose is to be connected to the prepared plateau surface of the proximal tibia. The tibial component is C-shaped by having an opening extending from the posterior part of its side wall to its center. (Exh. P-5)

72. There is no C-shaped groove in the upper articulating surface of the Howmedica 6439 knee that follows the C-shaped plan of the component. (Exh. DX-74) Said exhibit also shows two concave tracks in the upper plateau surface, neither of which is C-shaped nor have a uniform cross-sectional shape and shallow depth throughout their length. Nor does the 6439 knee have in each transverse cross-section a curve forming part of **[**25]** a circle of constant cross-section. The C-shaped groove located on the upper surface of a tibial component is critical to the "731 patent.

73. Howmedica's 6439 knee prosthesis does not allow for the same amount of rotation as the prosthesis shown and described in the "731 patent in suit. The bridge or plateau of the 6439 knee restrains axial rotation, which has a beneficial effect. In the human knee, rotary motion is constrained by the cruciate, by the collateral ligament and by the structure of the tibia, which does have a tibial ridge that restricts rotation. Although the tibial component of the 6439 knee may not restrict rotation during less active periods of human motion, more active motions will result in restricted motion by the Howmedica knee. Consequently, the human knee does rotate enough to permit the condylar surfaces to engage the bridge so that it does restrict axial rotation.

74. The two C-shaped grooves, or alternatively the interrupted C-shaped groove of defendant's tibial component, are the structural and functional equivalents of the C-shaped groove of the tibial component of patentees' claimed invention.

75. The two C-shaped grooves, or alternatively the **[**26]** interrupted C-shaped groove, in the upper surface of the defendant's tibial component, in combination with the two support

members of defendant's femoral component as described above, perform substantially the same function in substantially the same way to obtain the same result as do the tibial and femoral components of the claimed invention of the patent in suit.

76. Defendant's femoral component is a unitary integrally formed device constructed and adapted to be connected to the distal end of the femur and to serve in lieu of the condyle surfaces thereof. (Exh. P-5)

77. For implantation in the femur shaft, defendant's femoral component has an upper part provided with an upwardly directed bone fixation element for upward implantation in the femur shaft. (Exh. P-5)

78. Defendant's femoral component is provided with three fins. Two fins extend upwardly from the upper surface of the condyle replacing members of the component and have upwardly facing edges. The third fin is of triangular shape and extends upwardly from the upper surfaces of the condyle replacing members at the anterior portions thereof. The third fin has upwardly converging upper edges extending from the anterior **[**27]** parts of the upper edges of the first two fins. (Exh. P-5)

79. Defendant's 6439 Total Knee Femoral Component has a pair of transversely spaced apart support members. These serve in lieu of the knee's natural condyles and each has a downwardly facing bearing surface. The transverse cross-sectional shape of such downwardly facing bearing surfaces is a curve forming part of a circle and of shallow depth. (Exh. P-5)

80. The anterior to posterior shape of each bearing surface is defined by a continuous series of curves, two in number. (Exh. P-5) Claims 1 and 2 of the "731 patent require that the surface curve of its condyles have continuously changing radii or an infinite number of radii. The Howmedica 6439 knee does not have a continuously changing curve of constantly decreasing radii.

[*857] 81. The condylar bearing surfaces of the defendant's femoral component perform the equivalent function in the same manner and achieve the same result as do the bearing surface of the femoral component of the claimed invention of the Waugh Patent. During the prosecution of the patent, Wright argued the criticality of the recitation describing the shape of its femoral condyles as a grounds **[**28]** for issuing the patent. Wright inserted the recitation, in all its claims reciting a femoral component, that its condyles have a "continuously changing curve of constantly decreasing radii" while confronted with prior art rejections by the Patent Office.

82. In order to obtain allowance of claim 1, the inventors recited among the elements of the claim the following features:

(a) "each of said support members having a downwardly facing bearing surface the anterior to posterior shape of which is a continuously changing curve of constantly decreasing radii";

(b) "the tibial component having a groove in its upper surface which is C-shaped in plan, following the C-shape of the component";

(c) "the groove being of uniform cross sectional shape and shallow depth throughout its length"; and

(d) "its bottom being shaped in each transverse cross section as a curve forming part of a circle." (Exh. DX-2, 95) The underlined portion set forth in subparagraph (a) was set forth in the original claim 2 as filed. The underlined portion of subparagraph (b) was in original claim 10.

83. In order to obtain allowance of claim 2, the inventors recited among the elements of the claim the following **[**29]** feature:

(a) "a continuously changing curve of constantly decreasing radii." (Exh. DX-3, 96)

84. In order to obtain allowance of claim 3, the inventors recited among the elements of the claim the following features:

(a) "A shallow groove in the upper surface of the device extending throughout substantially the entire length thereof";

(b) "and therefore also being C-shaped"; and

(c) "the groove being of uniform cross sectional shape and depth and in each of its cross sections its bottom being formed as a curve forming part of a circle." (Exh. DX-4, 97)

85. The downwardly facing bearing surfaces 6 and 8 shown in Figs. 1 and 2 of the original drawings of the patent in suit were described in the original specification as being comprised of a continuous series of curves wherein each increment of curvature has a single radius and wherein the radii of the increments diminish from the anterior to posterior ends of such bearing surfaces (see column 2, line 66 to column 3, line of the patent in suit).

86. The downwardly facing bearing surfaces 6 and 8 shown in Figs. 1 and 2 of the original drawings of the patent in suit were described in the original specification as being formed of a **[**30]** continuous series of curves of constantly diminishing radii from the anterior portion of the curve at C to the posterior portion at D (see column 2, lines 58-61 of the patent in suit), and were so claimed in claim 2 as originally filed. (Exh. DX-5)

87. The language referred to in the foregoing paragraphs describes the downwardly facing bearing surfaces of the transversely spaced apart support members serving in lieu of the natural condyles of defendant's 6439 Total Knee Femoral Component as described supra.

CONCLUSIONS OF LAW

I. PATENTABILITY OF THE KNEE.

HN1 The statutory conditions of patentability, as set forth in 35 U.S.C. §§ 101-103, are novelty, utility and nonobviousness. The parties to this action agree that the subject matter of the patent at issue was utile. Therefore, the present controversy centers on the questions of novelty and obviousness.

A. Novelty.

HN2 Novelty or newness of an invention or discovery is the keystone to HN3 patentability. **[*858]** Section 102 of the Patent Act sets forth the types of activity which negate novelty and render an invention or discovery unpatentable. The pertinent provision of the Act provides:

"A person shall be entitled to a patent **[**31]** unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States ..."

The defendant Howmedica contends that the patent on the UCI knee is invalid for lack of novelty, because there was public use, sales and printed publication of the product prior to the critical date. If any one of Howmedica's assertions is correct, then the patent is invalid.

HN4 The "critical date" indicates the commencement of the one year grace period during which an inventor has the opportunity to engage in commercial activity without prejudice to his right to secure a patent. 35 U.S.C. § 102(b); In Re Theis, 610 F.2d 786 (C.C.P.A.1979). The existence and length of this period reflects a balance of (1) the inventor's interest in determining whether or not a patent is desired following sales and in having a sufficient amount of time to prepare and file a patent application, with (2) the public interest in preventing an inventor from concealing his invention from the public, while using it to his commercial advantage more than **[**32]** one year prior to his patent application, and thus extending the period of his monopoly beyond that protected by the patent laws. Cali v. Eastern Airlines, Inc., 442 F.2d 65, (2d Cir. 1971); Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516 (2d Cir.), cert. denied, 328 U.S. 840, 66 S. Ct. 1016, 90 L. Ed. 1615 (1946).

These competing interests led Congress to permit an inventor to make "public use" or to sell his invention for one year prior to the filing of a patent application. These same considerations, however, have led to a judicial gloss on the phrase "in public use or on sale," allowing certain uses or sales which are experimental in nature. City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126, 134, 24 L. Ed. 1000 (1878); In Re Yarn Processing Patent Validity Litigation, 498 F.2d 271, 277 (5th Cir.), cert. denied, sub nom. Sauquoit Fibers Co. v. Leesona Corp., 419 U.S. 1057, 95 S. Ct. 640, 42 L. Ed. 2d 654 (1974). HN5 The purpose of the "experimentation" exception to the § 102(b) bar is "to allow the inventor sufficient time to perfect his invention.... An invention is "perfected' for purposes of patentability once it has been reduced **[**33]** to practice by sufficient testing and experimentation to demonstrate its utility." In Re Yarn Processing, 498 F.2d at 281. Thus, the use by an inventor, in good faith, for the purpose of testing his apparatus before it has been reduced to practice, is not a public use within the scope of the statute, even if accidental to such use he derives some financial return. Similarly, a sale which meets the same qualifications will not render a product unpatentable. In Re Theis, 610 F.2d at 792.

Howmedica's claim that the UCI knee patent is invalid because of a public use is based upon the first implantation of the UCI knee in a living human on January 12, 1972, thirteen months prior to the filing of the application for the patent. The implantation, performed on a Mr. Jessen, attracted the attention of the news media, and certain accounts of it were published.

The plaintiffs do not deny that the implantation occurred, or that it occurred prior to the critical date. Rather, the plaintiffs claim that the use was experimental, and therefore did not render the knee unpatentable. HN6 In proving the experimental nature of the use of the knee, the patent owner has the burden, which must be satisfied **[**34]** by clear and convincing evidence. Smith and Griggs Manufacturing Co. v. Sprague, 123 U.S. 249, 264, 8 S. Ct. 122, 129, 31 L. Ed. 141 (1887); In re Theis, 610 F.2d at 792. The court is satisfied that this burden has been met by the plaintiffs.

[*859] Howmedica asserts that the structure of the prosthesis was perfected for purposes of patentability prior to the Jessen operation, or at most two weeks thereafter. The testimony

adduced at trial, however, demonstrated that the motives of the doctors in performing the implantation were noncommercial and that their motives comported with the need for additional testing to perfect the discovery. See Lear Siegler, Inc. v. Ark-Ell Springs, Inc., 569 F.2d 286, 290-91, 197 U.S.P.Q. 273, 276 (5th Cir. 1978). Therefore, the use of the knee occurring prior to the critical date was experimental in nature and does not mandate a finding of patent invalidity.

Howmedica also asserts that the patent is invalid because of sales or offers to sell prior to the critical date. HN7 A single instance of sale or offer to sell prior to the critical date will render a patent invalid. Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 24 L. Ed. 68 (1877); **[**35]** In Re Theis, 610 F.2d at 791; Timely Products Corp. v. Arron, 523 F.2d 288, 302 (2d Cir. 1975). Notwithstanding facts sufficient to raise the statutory "on sale" bar, a patent may be valid if the sale or offer to sell was primarily for the purpose of experimentation. City of Elizabeth v. American Nicholson Pavement Co., supra; DeLong Corp. v. Raymond International, Inc., 622 F.2d 1135, 1144 (3d Cir. 1980).

The court finds that the disputed sale was primarily for the purpose of experimentation, and, therefore, the patent is not rendered invalid thereby. (See Findings of Fact 22-29.)

As a third ground for patent invalidity under 35 U.S.C. § 102(b), Howmedica claims that a description of the invention was contained in certain "printed publications" prior to the critical date. In support of this allegation, Howmedica points to several newspaper articles containing information about the implantation operation performed on Mr. Jessen, as well as an oral and visual lecture by Drs. Waugh and Smith before a meeting of the California Medical Association.

HN8 A printed publication prior to the critical date which describes the invention will preclude entitlement to a patent. 35 U.S.C. § **[**36]** 102(b). HN9 To constitute a publication, within the meaning of the statute, the invention must be described sufficiently to impart to a person with ordinary skill and knowledge of the prior art the information needed to devise the invention without further genuine inspiration or undue experimentation. Seymour v. Osborne, 78 U.S. 516, 20 L. Ed. 33 (1871); Struthers Scientific & International Corp. v. Rappl & Hoenig Co., 453 F.2d 250, 255 (2d Cir. 1972); Philips Electronic and Pharmaceutical Industries Corp. v. Thermal and Electronics Industries, Inc., 450 F.2d 1164, 1169 (3d Cir. 1971). HN10 The publication bar is based upon the theory that an idea once published is in the public domain, and that no consideration can be offered thereafter in exchange for the grant of a patent monopoly. Pickering v. Holman, 459 F.2d 403, 407 (9th Cir. 1972). For this reason, and for the protection of the reasonable expectations of the public, the "experimental use" doctrine does not apply to overcome the printed publication bar. Id.

The evidence in this case demonstrates that neither the newspaper articles nor the lecture constituted printed publications within the meaning of 35 U.S.C. § 102(b). The implantation **[**37]** performed on Mr. Jessen attracted the attention of the news media and certain accounts of it were published. n2 The articles, however, did not bring the invention into the public domain, insofar as they did not sufficiently describe the invention or meet the standards enunciated above.

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n2. The success of the operation on Mr. Jessen, together with a brief description of the new prosthesis and its manufacturer were reported in the Associated Press article in the Long Beach Press Telegram on January 12, 1972. The following day, an article appeared in the Japanese Asahi Evening News. Several days later, a German newspaper carried a brief article. An article in the Bergen County Record in New Jersey appeared in early February.

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The lecture delivered before the California Medical Association was attended by **[*860]** approximately thirty persons. Dr. Smith's presentation dealt mainly with the development of the UCI knee. In connection with this lecture, he displayed projections of certain slides which showed **[**38]** pictures and drawings of the knee. Although slides can constitute printed publications, Philips Electronic & Pharmaceutical Industries Corp. v. Thermal and Electronics Industries, Inc., 450 F.2d 1164, (3d Cir. 1971) (microfilm), the projection of the slides at the lecture was limited in duration and could not disclose the invention to the extent necessary to enable a person of ordinary skill in the art to make or use the invention. In this regard, it is important to note that the public did not have access to the slides prior to the critical date, and that no prints of the slides were made prior to said date. Therefore, there is no evidence that the "publication" was disseminated or otherwise made available to the extent that persons interested in the information could locate it and put to use the essentials of the claimed invention. See I. C. E. Corp. v. Armco Steel Corp., 250 F. Supp. 738, (S.D.N.Y.1966).

B. Obviousness.

HN11 Section 103 of the Patent Act of 1952, 35 U.S.C. § 103 (19xx), provides:

> "s 103. Conditions for patentability; non-obvious subject matter
>
> "A patent may not be obtained ... if the differences between the subject matter sought to be patented and **[**39]** the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Patentability thus depends upon the "non-obvious" nature of the "subject matter sought to be patented" to a person having ordinary skill in the prior art. Graham v. John Deere Co., 383 U.S. 1, 14, 86 S. Ct. 684, 692, 15 L. Ed. 2d 545 (1966). This condition lends itself to several factual inquiries:

> "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." Id. 383 U.S. at 17, 86 S. Ct. at 693.

In addition, "secondary considerations" such as "commercial success, long felt but unsolved

needs, failure of others, etc." may be relevant as indicia of obviousness. Id. 383 U.S. at 17-18, 86 S. Ct. at 693.

Before making these factual **[**40]** inquiries, the court notes that HN12 a presumption of validity generally attaches to a patent, and the burden of proving invalidity rests upon the defendant. 35 U.S.C. § 282; Tokyo Shibaura Electric Co. v. Zenith Radio Corp., 548 F.2d 88, 93 (3d Cir. 1977). Howmedica, however, contends that the statutory presumption of validity does not apply in this case because certain prior art was not considered by the Patent and Trademark Office. See Aluminum Company of America v. Amerola Products Corp., 552 F.2d 1020, 1024 (3d Cir. 1977). The degree to which Howmedica is correct depends upon a balancing of the pertinence of the newly cited art against the pertinence of the art actually considered by the Patent Office. Id. at 1025. Having reviewed the prior art references cited by Howmedica in light of the prior art references considered by the Patent Office, the court finds as a matter of fact that none of the prior art relied upon by Howmedica is more pertinent to the subject matter of the Waugh Patent than that cited by the examiner in the course of prosecution of the patent. (Findings of Fact 60-62). Therefore, in analyzing Howmedica's claim of invalidity of the patent for obviousness, the **[**41]** court begins with a presumption of validity of the patent, which must be overcome by clear and convincing evidence. Id. at 1024.

The court has considered all of the prior art brought to the court's attention by the parties. Specifically, the court has considered such evidence as the Geomedic knee (which is the Averill patent), the Polycentric knee (the Gunston reference), the Der **[*861]** Chirung article, Drs. Frankel's and Burstein's work on instant centers, the St. Georg Sled (the Link patent), the MGH prosthesis, and the Johnston Patent.

After considering this evidence, the court has determined that there are significant differences between the prior art and the elements set forth in the various claims of the Waugh Patent. These differences between the combination of elements set forth in the several claims of the Waugh Patent and the prior art are not such that said combination as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the orthopaedic or biomechanic arts. Therefore, the court finds that the patent is not invalid for obviousness.

Because the statutory conditions of patentability set forth in 35 U.S.C. §§ **[**42]** 101-103 are satisfied, the court finds that the subject matter of the Waugh Patent was patentable. The court must determine, however, whether the patent was properly obtained.

II. PLAINTIFF'S CONDUCT IN SECURING THE PATENT.

Howmedica asserts that the Waugh Patent is invalid as a result of certain conduct of Wright and the doctor-inventors while the patent was pending before the Patent Office. Howmedica claims that the patent was procured fraudulently in that false representations of fact were made in the patent application and that relevant prior art was not disclosed to the Patent Office. Howmedica further presses its case for invalidity alleging that the declaration form was executed-in-blank and that certain post-oath revisions were made in the application.

A. Fraud.

HN13 Fraud in the procurement of a patent is a valid defense in a suit for patent infringement. Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 65 S. Ct. 993, 89 L. Ed. 1381 (1945). This defense is based upon the "social and economic consequences of a patent" which "give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from **[**43]** fraud or other inequitable conduct." Id. 324 U.S. at 816, 65 S. Ct. at 998. HN14 An applicant for a patent,

therefore, is held to the highest standards of honesty and candor in presenting his bid for a patent to the Patent Office. Norton v. Curtiss, 57 C.C.P.A. 1384, 433 F.2d 779, 167 U.S.P.Q. 532 (C.C.P.A.1970); 37 C.F.R. 1.56. n3 In this regard, "there is no rational basis for a distinction between affirmative misrepresentations and misleading omissions." Monsanto Co. v. Rohm & Haas Co., 312 F. Supp. 778, 793 (E.D.Pa.1970), aff'd, 456 F.2d 592 (3d Cir.), cert. denied, 407 U.S. 934, 92 S. Ct. 2463, 32 L. Ed. 2d 817 (1972). If such misrepresentations or omissions are present, they must be material in order to affect the validity of the patent. Monsanto, 312 F. Supp. at 794; Chromalloy American Corp. v. Alloy Surfaces Co., 339 F. Supp. 859, 873 (D.Del.1972). The test of materiality, however, is a liberal one. Norton v. Curtiss, supra. In addition to misrepresentations which are material, a finding of fraud must be based upon a finding of, at the least, gross negligence or recklessness in representing the facts to the Patent Office. DeLong Corp. v. Raymond International, Inc., 622 F.2d **[**44]** 1135, 1145-46 (3d Cir. 1980).

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HN15 n3. Presently, 37 C.F.R. 1.56 states that:

"A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantially involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application."

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Howmedica contends that the patent application was misleading in that (1) two **[*862]** affiants, **[**45]** Drs. McFarland and Tooms, overstated their qualifications and their knowledge of the state of the art, (2) one or more of the affiants stated falsely that the Polycentric knee had no rotational characteristics, that the UCI knee had a single so-called J-curve whereas the other references have the two J-curves positioned end-to-end, and that Howmedica had made an exact copy of the invention, (3) relevant prior art was omitted from the application, and (4) certain statutory bars to patentability were not disclosed, such as prior public use, sale or printed publication.

The court has considered these allegations separately and as a whole, and finds that the plaintiffs did not procure the patent on the Waugh knee fraudulently or inequitably. (Findings of Fact 58-70).

B. Post-Oath Revisions to the Patent Application.

Howmedica further challenges the validity of the Waugh Patent on the ground of fraud and inequitable conduct in the procurement of the patent. This challenge arises out of the failure of the inventors to read the patent application prior to executing and swearing to the Declaration, and the existence of alterations made to the application without the knowledge or approval **[**46]** of the inventors.

On November 14, 1972, the inventors executed and swore to the Declaration, Power of Attorney and Petition in blank without an attached corresponding completed application. That

Declaration stated:

> "NOTE: This form may be executed only when attached to a complete application as the last page thereof."

Although a draft may have been in existence and present when the Declaration was executed, it was not the application which was eventually filed with the Patent Office. Furthermore, there were changes made to the patent application subsequent to November 14, 1972. The Declaration, however, was not re-executed and was filed with the final application on February 14, 1973. There was no evidence at trial to show that the completed application, as filed, was ever viewed or reviewed by the inventors prior to filing with the Patent Office.

The plaintiffs do not contend that such conduct was proper. It cannot be gainsaid that plaintiffs' action in prosecuting the patent application was improper and would provide a sufficient basis to support a finding of patent invalidity. The rules of the Patent Office, of which the plaintiffs are charged with knowledge, **[**47]** stated that:

> "Any HN16 application signed or sworn to in blank, or without actual inspection by the applicant, and any application altered or partly filled in after being signed or sworn to ... may be stricken from the files." 37 C.F.R. § 1.56 n4

> 4. The present rule is substantially the same. See 37 C.F.R. § 1.56(c) (1980).

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The failure of the plaintiffs to adhere, whether intentionally or not, to the dictates of this rule is a matter which this court neither approves nor condones. Nevertheless, the court finds, albeit reluctantly, that the changes made in the application were not substantial changes and were not made with any intent to deceive or mislead the Patent Office or the public. For that reason, the post-oath revisions do not render the patent invalid. Halliburton Co. v. Dow Chemical Co., 514 F.2d 377 (10th Cir. 1975).

The court's decision that the patent is valid in the face of such improper conduct should not be misunderstood. Although the materiality of an alteration of an application weighs heavily in determining whether or not a patent application should be stricken, this **[**48]** consideration should play absolutely no role in determining the standard of propriety for an attorney prosecuting an application. Vandenberg v. Reynolds, 46 C.C.P.A. 938, 268 F.2d 744, 747 (C.C.P.A.1959).

III. INFRINGEMENT.

Having determined that the patent is valid, the court next considers plaintiffs' claim that the defendant unlawfully infringed the "731 patent by manufacturing the 6439 knee prosthesis.

HN17 The burden of proving infringement by a preponderance [*863] of the evidence rests upon the plaintiff. Fruehauf Corp. v. International Terminal Operating Co., 183 U.S.P.Q. 526 (D.N.J.1973), aff'd per curiam, 184 U.S.P.Q. (BNA) 266 (3d Cir. 1974). HN18 The standard of infringement is not whether the embodiment of the patent is infringed, but whether the claims of the patent are infringed. Here, Wright has charged Howmedica with infringement of claims 1, 2 and 3.

Plaintiffs argue first that the claims of the Waugh Patent read literally upon the Howmedica HN19 knee. To establish infringement, each element in the patent claim must be incorporated in the accused device. Q-Tips, Inc. v. Johnson & Johnson, 207 F.2d 509, 511 (3d Cir. 1953), cert. denied, 347 U.S. 935, 74 S. Ct. 630, [**49] 98 L. Ed. 1086 (1954). The documentary and testimonial evidence did not establish that the Howmedica knee has all of the essential elements recited in the patent claims. The condyles of its femoral component do not contain a "continuously changing curve of constantly decreasing radii", nor does the Howmedica tibial component have a "groove in its upper surface which is C-shaped in plan." The two articulating surfaces are neither of "uniform cross-sectional shape" nor of "shallow depth throughout its length." Because these elements of the Waugh Patent are not incorporated into the allegedly infringing device, it cannot be said that the claims of the patent read literally upon the Howmedica knee.

As a fallback argument, plaintiffs contend that even if the claim language does not read upon the accused device, the accused device nevertheless is comprised of elements which perform substantially the same functions in substantially the same way to obtain the same result as do the elements of the claimed invention. Thus, according to the plaintiffs, the doctrine of equivalents can be summoned to establish infringement.

HN20 The doctrine of equivalents protects a patent holder from devices that [**50] differ merely in name, form or shape from the patented invention. Ziegler v. Phillips Petroleum Co., 483 F.2d 858 (5th Cir.) cert. denied, 414 U.S. 1079, 94 S. Ct. 597, 38 L. Ed. 2d 485 (1973). Thus, minor deviations from the literal scope of the patent claims will not elude the reach of the patent's protection. Id. at 868.

HN21 In some situations, however, it is unnecessary to reach the issue of equivalence. In these situations, the history of the prosecution of the patent, contained in a "file wrapper," reveals that the patentee has surrendered claims, or has amended, narrowed, or otherwise limited his claims in response to objections of the Patent Office. HN22 If an applicant consents to the demands of the Patent Office in order to obtain the patent, such consent operates as a disclaimer, and the applicant is thereafter bound by it. Id. at 870; see Capri Jewelry, Inc. v. Hattie Carnegie Jewelry Enterprises, Ltd., 539 F.2d 846, 850-51 (2d Cir. 1976). HN23 The doctrine of "file wrapper estoppel," therefore, precludes a patent holder from later recapturing the breadth which was given up in the Patent Office to secure approval of the application. Exhibit Supply Co. v. Ace Patents Corp., 315 [**51] U.S. 126, 62 S. Ct. 513, 86 L. Ed. 736 (1942); P. Rosenberg, Patent Law Fundamentals, § 17.07(2) (1980).

Howmedica asserts the doctrine of file wrapper estoppel as a ground for holding that the Waugh Patent was not infringed. After reviewing the evidence, the court finds that the plaintiffs did make certain representations to the Patent Office to which they are now bound. These representations, in effect, limited the scope of the patent, and because of these limitations, the court finds that the defendant's knee was not an infringing device.

In order to obtain allowance of each of the claims, the inventors recited among the elements of the claim certain features. (See Findings of Fact 82-84.) For example, the inventors inserted into the claims concerning the femoral component that the shape of the condyles could be defined as "a continuously changing curve of constantly decreasing radii from the front to the rear of the component." In addition, the patentability [*864] of the tibial

component resided in the "C-shaped curve in its upper surface" and in the "constantly curved cross sectional shape" in an effort to distinguish the device from the prior art. These substantial **[**52]** assertions, among others, to the claims of the application after it was rejected over prior art, estop the plaintiffs from arguing that either the language of the claim or the doctrine of equivalents allows the scope of the patent sufficient breadth to permit a finding of infringement in this case.

The court, therefore, finds no infringement, even if the infringing device is the equivalent of plaintiffs' claims.

IV. ATTORNEYS' FEES.

The plaintiffs and the defendant have moved for an award of attorneys' fees pursuant to 35 U.S.C. § 285. That section provides for such an award "in exceptional cases." Plaintiffs' application is based upon an allegation that the infringement was willful. Although defendant's conduct was willful, said willfulness is immaterial by reason of the finding of non-infringement. Defendant, on the other hand, seeks fees based upon allegations of fraud and inequitable conduct in the procurement of the patent. See Etten v. Lovell Manufacturing Co., 225 F.2d 844, 849 (3d Cir. 1955), cert. denied, 350 U.S. 966, 76 S. Ct. 435, 100 L. Ed. 839 (1956); Kahn v. Dynamics Corporation of America, 508 F.2d 939, 945 (2d Cir. 1975), cert. denied 421 U.S. 930, 95 S. Ct. **[**53]** 1657, 44 L. Ed. 2d 88 (1975). For the reasons stated above, however, the court has found neither fraud nor inequitable conduct. Therefore, because the award of attorneys' fees is to be used sparingly, W. L. Gore & Associates Inc. v. Oak Materials Group, 424 F. Supp. 700, 703 (D.Del.1976), and because this case is not "exceptional" within the meaning of § 285, the court finds that neither party is entitled to costs or counsel fees.

For the foregoing reasons, judgment shall be entered in favor of the defendant on the complaint without costs or counsel fees to either party.